REMARKS

Claims 21-43 are pending. Claims 21-43 were rejected under §103(a) in view of various prior art references. Claims 21, 32, 36 and 40 are independent.

Claim Rejections 35 U.S.C. §103

A. Claims 21-25, 28, 31 and 40

Claims 21-25, 28, 31 and 40 were rejected as obvious under 35 U.S.C. §103(a) by Brown (U.S. Patent No. 6,161,095) in view of Barrett (U.S. Patent No. 6,175,779). The Applicant respectfully traverses the foregoing rejection.

The Applicant respectfully asserts that the Examiner has failed to present a *prima facie* case for obviousness over the cited references for five reasons, (1) the Examiner has failed to provide a motivation to combine the cited references; (2) there is no motivation to combine the Brown and Barrett references; (3) the Barrett reference is non-analogous art; (4) adding the identified feature from Barrett to Brown does not result in the claimed invention; and (5) adding the identified feature in Barrett to Brown leads to an unworkable device and is therefore impossible.

The Examiner has provided no evidence indicating a motivation to combine the Brown and Barrett references. In describing the current §103(a) rejection the Examiner has merely stated that:

> "one of ordinary skill in the art would have been motivated to modify the portable device (112) in Brown and the emergency medical recordation feature as taught in Barrett in order to provide the user of the system of Brown with a means of recording emergency events in which medication is administered."

The Examiner's asserted motivation to combine is merely a circular argument that uses hindsight to attempt to arrive at Applicant's claimed invention. The quoted passage only states that a person of ordinary skill in the art would be motivated to add the "emergency medical recordation feature" to Brown as a means of adding emergency recording to Brown. The Examiner has failed to demonstrate where the prior art teaches a motivation to make the identified combination.

In fact, there is no motivation to combine Brown and Barrett as the Examiner has. The "emergency medical recordation feature" identified by the Examiner in Barrett is ***not*** disclosed for the purpose of recording an unforeseen medical treatment, as recited in the Applicant's claims. Rather, Barrett discloses emergency dispensing to solve a problem particular to the Barrett system itself. Barrett teaches a medication dispenser that mechanically dispenses medication in accordance with prescriptions preprogrammed into the system by a pharmacist. (Barrett, 3/45-60). Barrett also discloses that security preventing unauthorized access to the medication in the dispenser is an important aspect of the disclosed system. (Barrett, 2/29-33; 2/50). Thus, the medication dispenser disclosed by Barrett tightly controls the medication within the device. Accordingly, Barrett must disclose an override mechanism for the nurse to get medication out of the dispenser to "administer emergency dosages of medications that are not contained in the patient's current medication information." (Barrett, 4/49-52). Without this override, medical professionals would not be able to get medication out of the dispenser during emergencies.

In contrast, Brown discloses a device that does not actually dispense medication, thus there is no need for an emergency override of the Brown system. Moreover, Brown is chiefly concerned with assuring compliance with a pre-prescribed treatment regimen, thus it offers no

contemplation of emergency treatments. Brown's title is "***Treatment Regimen Compliance*** and Efficacy With Feedback." (*emphasis added*). It is only with the impermissible hindsight recognition of Applicant's invention that one would even consider combining Brown's treatment regimen compliance and Barrett's medication dispenser cart as the Examiner has.

Beyond the lack of a motivation to combine Brown and Barrett, Barrett itself fails as a proper §103 reference because it from a non-analogous art. Hospital medication dispensers like the one disclosed by Barrett have no reasonable connection to patient operated medication logging devices like those claimed by Applicant. Barrett's medication dispenser is a large cart used by medical professionals to accurately dispense medication to numerous patients in a hospital ward. In contrast, Applicant's claims are directed to a portable device used by patients in their daily lives to keep track of their ***self-administration*** of a medical treatment, and to provide the recorded details about their treatment to medical professionals. Thus, Barrett is neither "in the field of applicant's endeavor," nor is it "reasonably pertinent to the particular problem with which the inventor was concerned." *MPEP § 2141.01(a)*. Clearly, Barrett is not concerned with allowing a patient to create and communicate accurate records of medical treatments to medical professionals, the Barrett system is used by medical professionals themselves.

In addition, the combination of Brown and Barrett does not provide all the limitations of claims 21-25, 28, 31 and 40. Neither Brown, Barrett nor their combination disclose generating a record of a "patient's unforeseen self administration of a medical treatment." Brown only discloses a treatment compliance device that ensures the user is complying with a preprogrammed treatment. Thus, Brown does not contemplate recording a patient's unforeseen

self administration of a medical treatment. Brown does not contemplate or disclose a system that is programmed to log a patient's self administered, symptomatic, medication usage.

Similarly, Barrett discloses a medication dispenser that allows a ***nurse*** to override the patient's normal prescription to dispense "medications that are not contained in the patent's current medication information" in response to an emergency. (Barrett, 4/49-52). Thus, Barrett also does not disclose recording a patient's unforeseen ***self administration*** of a medical treatment. Moreover, Barrett's does not contemplate the purpose of the claimed invention, which is to record, outside of a medical environment, a patient's self administration of medication in order to provide a log that can be studied by the patient's medical provider. In fact, Barrett cannot contemplate the need to create such a treatment log because the emergency treatment disclosed in Barrett is performed by medical professionals.

Finally, it is impossible to add the emergency medication dispensing element of Barrett to the compliance monitor of Brown to obtain a working device. Barrett records the emergency dispensation of medication. Brown, however, must be pre-programmed with the treatment regimen by a service provider. (Brown, 4/43-46). The Examiner relies on Barrett's ability to dispense "medications that are not contained in the patient's current medication information." (Barrett, 4/49-52). Barrett's medication dispensing cart, however, contains information concerning all the medications contained within it, not just the current regimen of a single patient, thus in an emergency it can record that a patient is receiving any one of the preprogrammed medications contained in the dispenser. (Barrett, 4/49-52). Accordingly, Brown has no way of recording "medications that are not contained in the patient's current medication information," because it ***only contains*** information concerning the patient's current medication information and has no pre-programming of hypothetical emergency medications that

a patient might take. Moreover, it is unreasonable to suggest that a small portable device at the time of the applicant's invention, such as the one disclosed in Brown, could be programmed and kept up to date regarding all possible "emergency treatments" the patient may require.

B. Claims 26, 27, 29, 30, 32-39 and 41-43

Claims 26, 27, 29, 30, 32-39 and 41-43 were rejected as obvious under 35 U.S.C. §103(a) over Brown in view of Barrett further in view of various other references. As discussed above, Brown in view of Barrett does not disclose the limitations of Applicant's pending claims as applied by the Examiner.

For the same five reasons discussed above, Applicant believes that the combination of Brown and Barrett is improper and fails to disclose recordation of a patient's "unforeseen self administration of a medical treatment."

Applicant further specifically objects to the Examiner's characterization of Goetz (U.S. Patent No. 6,421,650), directed to claims 27 and 37, as disclosing "tainted medication" warnings in its teaching of drug interaction warning. Drug interactions, are nothing like "tainted medication" warnings. Tainted medication means that the specific unit of medication used by the patient has been deemed unfit because of a problem with that specific unit of medication. In contrast, drug interactions result not because there is a problem with a specific unit of medication used by the patient, but rather because combining two medication types, which are safe individually, in unsafe. To provide a tainted medication warning each individual unit of medication must be tracked and monitored. In contrast, providing drug interaction warnings only requires medication types to be tracked. For example, to check for a drug interaction the system need only know that a patient is taking aspirin. In contrast, to check for a tainted medication the system needs to identify the specific bottle of aspirin the patient's pill came from.

Thus, a drug interaction system is much simpler and unable to provide "tainted medication" warnings.

Applicant further objects to the Examiner's official notice as applied to claims 41-43. The Examiner has taken official notice that the dependant claims' recitation of unforeseen events consisting of accidents, medical symptoms, and physical reactions are well known in the art. The Examiner, however, has merely recited that the dependant claims recite known species from the genus of "unforeseen events." The Examiner's notice, however, does not teach the claim limitations provided by these dependant claims, *i.e.*, the recordation of a patient's self administration of medication resulting from an unforeseen accident, medical symptom, or physical reaction. As noted above, the Examiner attempted to show the generic version of this limitation in the prior art through reference to the Barrett reference. Barrett, however, teaches a medical dispenser that dispenses medication in response a nurse's request during an ***emergency event***. The Examiner's official notice does not expand the teachings of Barrett to show that prior art demonstrates that it is well known to generate a record based on a patient's unforeseen self administered treatment of an accident, medical symptom, or physical reaction.

The above-discussed errors with respect to the Brown and Barrett apply to all the pending rejections. Applicant, therefore, does not address the Examiner's other representations with respect to how the additional dependent limitations are found in the cited prior art. Applicant reserves the right to address these additional arguments in the future.

CONCLUSION

Based on the foregoing amendments and remarks, Applicants respectfully request reconsideration and withdrawal of the rejection of claims and allowance of this application.

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. 13-4500, Order No. 4297-4017. A DUPLICATE OF THIS DOCUMENT IS ATTACHED.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. 13-4500, Order No. 4297-4017. A DUPLICATE OF THIS DOCUMENT IS ATTACHED.

Respectfully submitted,
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Dated: December 10, 2004 By: _____
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